WHAT IS CLAIMED IS:

1. A controlled release preparation comprising tramadol or a pharmaceutically acceptable salt thereof for oral administration.

2. A controlled release preparation as claimed in Claim 1 containing from about 50 to about 800 mg of tramadol (calculated as tramadol hydrochloride).

3. A controlled release preparation as claimed in Claim 1, having an in-vitro dissolution rate (measured by the Ph. Eur. Paddle method at 100 rpm in 900 ml 0.1 N hydrochloric acid at 37°C and using UV detection at 270 mm) as set forth below:

TIME (H)	% RELEASED
1	0-50
2	0-75
4	3-95
8	10-100
12	20-100
16	30-100
24	50-100
36	>80

4. A controlled release preparation as claimed in Claim 1, having an in-vitro dissolution rate (measured by the Ph. Eur. Paddle method at 100 rpm in 900 ml 0.1 N hydrochloric acid at 37°C and using UV detection at 270 mm) as set forth below:

TIME (H)	% RELEASED
1	20-50
2	40-75
4	60-95
8	80-100
12	90-100

5. A controlled release preparation as claimed in Claim 1, having an in-vitro dissolution rate (measured by the Ph. Eur. Paddle method at 100 rpm in 900 ml 0.1 N hydrochloric acid at 37°C and using UV detection at 270 mm) as set forth below:

TIME (H)	% RELEASED
1	0-50
2	0-75
4	10-95
8	35-100
12	55-100
16	70-100
24	>90

6. A controlled release preparation as claimed in Claim 1, having an <u>in-vitro</u> dissolution rate (measured by the Ph. Eur. Paddle method at 100 rpm in 900 ml 0.1 N hydrochloric acid at 37°C and using UV detection at 270 mm) as set forth below:

TIME (H)	% RELEASED
1	0-30
2	0-40
4	3-55
8	10-65
12	20-75
16	30-88
24	50-100
36	>80

7. A controlled release oral dosage form according to claim 1, comprising a therapeutically effective amount of tramadol or a salt thereof in a matrix adapted to provide a controlled release of the tramadol or salt thereof upon oral administration.

8. A dosage form according to claim 7, wherein said matrix comprises a controlled release matrix comprising at least one alkylcellulose, at least one C_{12} to C_{36}, aliphatic alcohol and, optionally at least one polyalkylglycol.

9. A dosage form as claimed in claim 8, wherein said optionally at least one polyalkylglycol is polyethylene glycol.

10. A dosage form according to claim 8, wherein said at least one C_{12} to C_{36} aliphatic alcohol is a C_{14} to C_{22} aliphatic alcohol.

11. A dosage form according to claim 8, wherein said alkylcellulose is a C_1-C_6 alkylcellulose.

12. A dosage form according to claim 8, characterized in that the dosage form contains from about 1 to about 20% w/w, preferably from about 2 to about 15% w/w of one or more alkylcelluloses.

13. A dosage form according to claim 8, wherein said aliphatic alcohol is selected from the group consisting of lauryl alcohol, myristyl alcohol, stearylalcohol, cetyl alcohol, cetostearyl alcohol, and mixtures of any of the foregoing.

14. The dosage form of claim 13, wherein said aliphatic alcohol is cetyl alcohol or cetostearyl alcohol.

15. A dosage form according to claim 8, wherein said dosage form contains from about 5 to bout 30% w/w of aliphatic alcohol.

16. A dosage form according to claim 8, wherein aid dosage form contains from about 10 to about 25% w/w of aliphatic alcohol.

17. A dosage form according to claim 1, in the form of film coated spheroids, wherein said spheroid matrix comprises a spheronizing agent, preferably microcrystalline cellulose.

18. A dosage form according to claim 1, in the form of multi-particulates wherein said matrix comprises a hydrophobic fusible carrier or diluent having a melting point from 35 to 140°C and optionally a release control component comprising a water soluble fusible material, or a particulate soluble or insoluble organic or inorganic material.

19. A dosage form according to claims 1, which comprises a tablet formed by compressing a multiparticulate according to Claim 18.

20. A process for the preparation of a solid, controlled release oral dosage form, comprising incorporating a therapeutically effective amount of tramadol or a pharmaceutically acceptable salt thereof in a matrix adapted to provide a controlled release of the tramadol or salt thereof upon oral administration.

21. A process according to claim 20, wherein from about 50 to about 800 mg of tramadol (calculated as tramadol hydrochloride) is incorporated in the dosage form.

22. A process according to claim 20, wherein the dissolution rate (measured by the Ph. Eur. Paddle method at 100 rpm in 900 ml 0.1 N hydrochloric acid at 37°C and using UV detection at 270 mm) is as set forth below:

TIME (H)	% RELEASED
1	0-50
2	0-75
4	3-95
8	10-100
12	20-100
16	30-100
24	50-100
36	>80

23. A process according to claim 20, wherein the dissolution rate (measured by the Ph. Eur. Paddle method at 100 rpm in 900 ml 0.1 N hydrochloric acid at 37°C and using UV detection at 270 mm) is as set forth below:

TIME (H)	% RELEASED
1	0-50
2	0-75
4	10-95
8	35-100
12	55-100
16	70-100
24	>90

24. A process according to claim 20, wherein the dissolution rate (measured by the Ph. Eur. Paddle method at 100 rpm in 900 ml 0.1 N hydrochloric acid at 37°C and using UV detection at 270 mm) is as set forth below:

TIME (H)	% RELEASED
1	0-50
2	0-40
4	3-55
8	10-65
12	20-75
16	30-88
24	50-100
36	>80

25. A process according to claim 20, wherein said matrix comprises a controlled release matrix comprising at least one C_1 to C_6 alkylcellulose, at least one C_{12} to C_{36}, aliphatic alcohol and, optionally at least one polyalkylglycol.

26. A process according to claim 25, wherein said aliphatic alcohol is a C_{14} to C_{22} aliphatic alcohol.

27. A process according to claim 25 wherein said optionally at least one polyalkylglycol is polyethylene glycol.

28. A process according to claim 20, wherein said at least one alkylcellulose is ethylcellulose.

29. A process according to claim 20, wherein said dosage form comprises from about 1 to about 20% w/w of one or more alkylcelluloses.

30. A process according to claim 29, wherein said dosage form contains from about 2 to about 15% w/w of one or more alkylcelluloses.

31. A process according to claim 20, wherein said aliphatic alcohol comprises lauryl alcohol, myristyl alcohol or stearyl-alcohol.

32. A process according to claim 31, wherein said aliphatic alcohol is cetyl alcohol or cetostearyl alcohol.

33. A process according to claim 20, wherein said dosage form comprises from about 5 to about 30% w/w of aliphatic alcohol.

34. A process according to claim 33, wherein said dosage form comprises from about 10 to about 25% w/w of aliphatic alcohol.

35. A process according to claim 20, further comprising:

(a) granulating a mixture comprising tramadol or a pharmaceutically acceptable salt thereof and one or more alkylcelluloses,

(b) mixing the alkylcellulose containing granules with one or more C_{12-36} aliphatic alcohols; and, optionally

(c) shaping and compressing the granules, and film coating, if desired.

36. A process according to claim 20, further comprising:

(a) granulating a mixture comprising tramadol or a pharmaceutically acceptable salt thereof, lactose and one or more alkylcelluloses with one or more C_{12-36} aliphatic alcohol; and, optionally,

(b) shaping and compressing the granules, and film coating.

37. A process according to claim 20, further comprising:

(a) granulating the mixture comprising tramadol or a pharmaceutically acceptable salt thereof and a spheronizing agent;

(b) extruding the granulated mixture to give an extrudate;

(c) spheronizing the extrudate until spheroids are formed; and

(d) coating the spheroids with a film coat.

38. A process according to claim 20, comprising:

(a) mechanically working in a high-speed mixer, a mixture of tramadol or a pharmaceutically acceptable salt thereof in particulate form and a particulate, hydrophobic fusible carrier or diluent having a melting point from 35 to 140°C and optionally a release control component comprising a water soluble fusible material, or a particulate soluble or insoluble organic or inorganic material at a speed and energy input which allows the carrier or diluent to melt or soften, whereby it forms agglomerates;

(b) breaking down the larger agglomerates to give controlled release seeds;

(c) continuing mechanically working with optionally a further addition of low percentage of the carrier or diluent; and

(d) optionally repeating steps (c) and possibly (b) one or more times.

39. A process according to claim 20, characterized by forming a drug mixture of dry active ingredient and fusible release control materials followed by mechanically working the mixture in a high speed mixer with an energy input sufficient to melt or soften the fusible material whereby it forms particles with the active ingredient.

40. A process according to claim 20, comprising compressing particles obtained by the process of claim 38.

41. A process according to claim 20, comprising compressing particles obtained by the process of claim 39.